

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in this application.

Listing of Claims:

1-17 (Canceled)

18. (Currently Amended) An apparatus for the delivery of a therapeutic agent to a predetermined site within a patient comprising:

means for the administration of said therapeutic agent to said patient, comprising a reservoir for the therapeutic agent, at least one orifice through which the agent is administered, and a controlled source of energy sufficient to transfer a predetermined amount of the therapeutic agent at a predetermined rate from said reservoir through said orifice to the predetermined site within the patient,

a plurality of penetrating electrodes arranged with a predetermined spatial relationship relative to said orifice;

means for generating an electrical signal operatively connected to said electrodes; and

~~The apparatus as recited in claim 1 further comprising~~ an extendable shield means for shielding either the agent orifice or the electrodes from a user of the apparatus when the orifice or the electrodes are not in contact with the patient.

19. (Original) The apparatus as recited in claim 18 wherein said extendable shield means includes at least one source of energy to extend said shield when the orifice or the electrodes are not in contact with the patient.

20. (Original) The apparatus as recited in claim 18 wherein said extendable shield means extends to shield either the agent orifice or the electrodes after the orifice or the electrodes are removed from contact with the patient.

21. (New) An apparatus for the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising:

means for the administration of said therapeutic agent to said patient, comprising a reservoir for the therapeutic agent, at least one orifice through which the agent is administered, and a first controlled source of energy sufficient to transfer a predetermined amount of the therapeutic agent from said reservoir through said orifice to the predetermined site within the tissue of the patient;

a plurality of penetrating electrodes arranged with a predetermined spatial relationship relative to said orifice; and

means for generating an electrical field which facilitates the delivery of said therapeutic agent within tissue, which means is operatively connected to said electrodes,

wherein the first controlled source of energy comprises at least one of a spring, compressed gas, or an electromechanical energy source.

22. (New) An apparatus to facilitate the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising: a plurality of penetrating electrodes operatively connected to a controlled source of energy sufficient to deploy the electrodes to a predetermined depth within the patient; and

means for generating an electrical field, which facilitates the delivery of said therapeutic agent within tissue, which means is operatively connected to said electrodes in their deployed state.

23. (New) An apparatus for the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising:

a plurality of penetrating electrodes operatively connected to means for generating an electrical field, which facilitates the delivery of said therapeutic agent within tissue at the predetermined site; and

a protective shield which is configured to extend over said electrodes following removal of said electrodes from said predetermined site within the tissue.

24. (New) The apparatus as recited in claim 23, wherein said protective shield is operatively connected to a source of energy sufficient to extend said protective shield over said electrodes.

25. (New) The apparatus as recited in claim 23, wherein said protective shield is precluded from accidental retraction once it is extended over said electrodes.

26. (New) An apparatus for the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising:

a housing including a plurality of penetrating electrodes having proximal and distal ends, each configured with an electrically conductive contact region at the proximal end;

means configured to deploy said penetrating electrodes to a predetermined depth within the patient;

electrode contact points in said housing configured for a mechanical interface with said conductive contact region of said penetrating electrodes; and

means for generating an electrical field which facilitates the delivery of said therapeutic agent, which means is operatively connected to said electrode contact points.

27. (New) The apparatus as recited in claim 26, wherein said contact points are comprised of an inert metal.

28. (New) The apparatus as recited in claim 27, wherein said inert metal is gold plated.

29. (New) The apparatus as recited in claim 26, wherein said contact points are conductive bands.

30. (New) The apparatus as recited in claim 26, wherein each of said electrodes is configured to maximize the mechanical interface between said conductive contact region and said electrode contact point.

31. (New) An apparatus for the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising:

means for the administration of said therapeutic agent to said patient comprising a reservoir for the therapeutic agent, at least one orifice through which the agent is administered, and means for transferring a predetermined amount of the therapeutic agent from said reservoir through said orifice to the predetermined site within the tissue of the patient;

a plurality of penetrating electrodes which are arranged to be deployable to a predetermined depth within the patient; and

means for generating an electrical field, which facilitates the delivery of said therapeutic agent, which means is operatively connected to said electrodes.

32. (New) An apparatus for the delivery of a therapeutic agent to cells in a predetermined site within the tissue of a patient comprising:

means for the administration of said therapeutic agent to said patient, comprising a reservoir for the therapeutic agent, at least one orifice through which the agent is administered, and a first controlled source of energy sufficient to transfer a predetermined amount of the therapeutic

agent from said reservoir through said orifice to the predetermined site within the tissue of the patient;

a plurality of penetrating electrodes operatively connected to a second controlled source of energy sufficient to deploy the electrodes to a predetermined depth within the patient; and

means for generating an electrical field which facilitates the delivery of said therapeutic agent, which means is operatively connected to said electrodes.

33. (New) The apparatus as recited in claim 32 wherein the first controlled source of energy to transfer the therapeutic agent is at least one of a spring, compressed gas, and electromechanical energy source.

34. (New) An apparatus for the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising:

a) means for the administration of said therapeutic agent to said patient comprising:

i) reservoir for the therapeutic agent,
ii) at least one orifice through which the agent is administered, and
iii) means for transferring a predetermined amount of the therapeutic agent from said reservoir through said orifice to the predetermined site within the tissue of the patient;

b) a plurality of penetrating electrodes arranged in a predetermined spatial relationship relative to said orifice;

c) means for generating an electrical field which facilitates the delivery of said therapeutic agent, which means is operatively connected to said electrodes; and

d) control means configured to provide a pre-determined temporal relationship between the administration of the agent and generation of the electrical field.

38. (New) The apparatus of claim 37, further comprising:

e) a user-activated trigger operatively connected to said control means wherein activation of said trigger initiates electrode and orifice insertion, agent administration, and electrical field application, all according to a predetermined timing and sequence.

37. (New) An apparatus assembly for the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising:

a) subassembly for the administration of said therapeutic agent within the tissue of said patient comprising

i) fluid reservoir operatively connected to an injection needle with at least one injection orifice and

ii) means for transferring a predetermined amount of the therapeutic agent from said reservoir through said orifice to the predetermined site within the tissue of the patient;

b) detachable electrode subassembly configured with a plurality of penetrating electrodes arranged in a predetermined spatial relationship;

c) structural means incorporating a user interface and operative connections for said detachable electrode subassembly, said fluid reservoir, and said injection needle wherein said structural means is configured to allow disposition of said plurality of electrodes and said injection orifice within the tissue of a patient according to a predetermined spatial relationship; and

d) means for generating an electrical field which facilitates the delivery of said therapeutic agent, which means is operatively connected to said electrodes.

38. (New) An apparatus assembly for the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising:

- a) subassembly for the administration of said therapeutic agent to cells in the tissue of said patient comprising a fluid reservoir operatively connected to an injection needle with at least one injection orifice; and
- b) electrode subassembly for the propagation of electrical fields within the tissue of said patient comprising a plurality of penetrating electrodes arranged in a predetermined spatial relationship;
- c) structural means incorporating a user interface and operative connections for said electrode subassembly, said fluid reservoir, and said injection needle wherein said structural means is configured to allow disposition of said plurality of electrodes and said injection orifice within the tissue wherein said injection orifice is positioned within the region of tissue bounded by said plurality of penetrating electrodes; and
- d) means for generating an electrical field which facilitates the delivery of said therapeutic agent, which means is operatively connected to said electrodes.

39. (New) An apparatus assembly for the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising:

- a) at least one subassembly for the administration of said therapeutic agent to the tissue of said patient, comprising a fluid reservoir operatively connected to at least one injection needle with at least one injection orifice;
- b) a plurality of penetrating electrodes;
- c) structural means incorporating a user interface and operative connections for said administration subassembly and said electrodes wherein said structural means is configured with a mechanism to facilitate transition of said injection needle and said electrodes from a retracted state within said structural means to a deployed state within the tissue of a patient; and

d) means for generating an electrical field which facilitates the delivery of said therapeutic agent, which means is operatively connected to said electrodes in their deployed state.

40. (New) An apparatus assembly for the delivery of a therapeutic agent to cells in a predetermined site within tissue of a patient comprising:

a) at least one subassembly for the administration of said therapeutic agent to cells in the tissue of said patient, each comprising a fluid reservoir operatively connected to at least one electrically conductive injection needle with at least one injection orifice;

b) at least one penetrating electrode

c) structural means incorporating a user interface and operative connections for said administration subassembly wherein said structural means is configured with a mechanism to allow transition of said injection needle and said penetrating electrode from a retracted state within said structural means to a deployed state in the tissue of a patient; and

d) means for generating an electrical field which facilitates the delivery of said therapeutic agent, which means is operatively connected to said conductive injection needle and said penetrating electrode in their deployed state.

41. (New) An apparatus assembly for the delivery of a therapeutic agent to a predetermined site within tissue of a patient comprising:

a) a plurality of penetrating electrodes wherein at least one of said electrodes is hollow having an orifice through which the therapeutic agent is administered from a fluid reservoir;

b) structural means incorporating a user interface and operative connections for said penetrating electrodes wherein said structural means is configured with a mechanism to allow transition of said penetrating electrodes from a retracted state within said structural means to a deployed state in the tissue of a patient; and

c) means for generating an electrical field which facilitates the delivery of said therapeutic agent, which means is operatively connected to said penetrating electrodes in their deployed state.